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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/774,935

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Nadja Jungmann

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SCULLY SCOTT MURPHY & PRESSER, PC  
400 GARDEN CITY PLAZA  
SUITE 300  
GARDEN CITY, NY 11530

EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

07/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/774,935	<b>Applicant(s)</b> JUNGMAN ET AL.	
	<b>Examiner</b> San-ming Hui	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendments filed March 23, 2009 have been entered.

Claims 1-10 are pending.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "free from porous materials and carrier materials" recited in claim 1 is not supported by the originally filed specification nor originally filed claims. Applicant is required to cancel the new matter.

#### ***Response to Arguments***

Applicant's arguments filed March 23, 2009 averring the support of the limitation being found in page 6, paragraph [0042] have been fully considered but they are not persuasive. The examiner notes that when closely examining the disclosure in [0042], the only carrier material excluded is the filler. There is no explicit disclosure implying all of the other carrier materials, for example solvents could be functioned as carrier, is excluded. The examiner further notes that the encapsulating materials can also be categorized as "carrier materials". For prior art searching purpose, the term "carrier

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materials” is construed as excipient that is inert and non-active with its sole purpose as a filler or vehicle.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,458,387 ('387) in view of JP07096166 A (herein after referred as '166, the reference is from the IDS filed 2/9/2004), also provided is the machine translation of '166's detailed description.

'387 teaches the use of microspheres for various purposes such as drug delivery and cosmetics (See col. 29, lines 10-12). '387 also teaches the use of microsphere to deliver various actives. '387 also teaches the use of Eudragit E100 as the coating polymer for forming the microspheres (See col. 36, Example 8 for example) and the pH of the resulting polymer solution is at pH 6.5. '387 teaches the protein component can be a therapeutic protein (col. 3, lines 51-52).

'387 does not expressly teach the microspheres would be degraded in the pH of the skin as 5.0 to 6.0. '387 does not expressly teach the molecular weight of the polymer employed.

'166 teaches microcapsules with the same copolymer (i.e., 2-dimethylaminoethyl methacrylate/methyl methacrylate/n-butyl methacrylate polymer) as useful in cosmetic product (See the abstract, paragraph [0035]). Various cosmetic ingredients such as vitamin C can be added [see paragraph 0022]). The microcapsules are designed being dissolved in the skin pH in the range of 4.5-6.5 (See paragraph [0048]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the microspheres of '387 in cosmetic composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the polymer herein claimed with the herein claimed MW.

One of ordinary skill in the art would have been motivated to employ the microspheres of '387 in cosmetic composition since it is known to be useful in cosmetic preparation. Cosmetics product employing the herein claimed polymer, i.e., Eudragit E100, is well-known to be dissolved in the skin pH as taught in '166. Furthermore, the optimization of the copolymer MW is considered within the purview of skilled artisan since changing the molecular weight would change the viscosity, solubility of the polymer. Absent evidence to the contrary, such formulation process is considered routine to one of ordinary skill in the art.

### ***Response to Arguments***

Applicant's arguments filed March 23, 2009 averring the cited prior art not excluding carrier materials have been fully considered but they are not persuasive. As discussed in the remarks above, the term "carrier materials" is construed as inert and

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non-active materials that functions as vehicle or carriers. In the case of '387, the carrier protein is not inert not non-active. Therefore, the cited prior art as a whole still renders the instant claims obvious.

Applicant's arguments filed March 23, 2009 averring the cited prior art's failure to teach non-porous materials have been considered, but are not found persuasive. As discuss in the previous office action, the cited prior art teaches the exact same polymer recited in the dependent claims. And such polymer is known to be useful in materials for making microspheres. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would have been motivated to employ the polymeric microspheres which is made of the polymer taught in '166 since employing such well-known polymer in making well-known pharmaceutical composition (microspheres) would exhibit the desirable properties (i.e., dissolved in the skin pH for example).

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui  
Primary Examiner  
Art Unit 1617

/San-ming Hui/  
Primary Examiner, Art Unit 1617

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